An Agency "Warning Letter" Does Not a Lawsuit Make: Sometimes a "Warning Letter" Is Really Just a Warning

Product Liability Advisory

April 2012 by Carol Brophy

Unfortunately, the number of consumer class action complaints brought against consumer product manufacturers under state consumer protection and/or false advertising law statutes continues to rise. This increase can be traced in part to some plaintiffs' counsel's ingenious efforts to build entire cases around purported violations found in Food and Drug Administration (FDA) or Federal Trade Commission (FTC) press releases, warning letters and complaints. To these attorneys, warning letters and press releases equal liability. Period. End of story.

Thus, after plaintiffs' counsel finds a potential violation and a willing plaintiff, he or she files suit alleging one of two things: (1) that the defendant made a label claim without having adequately tested the product or substantiated the claim (commonly called "prior substantiation"); or (2) that the plaintiff "in deciding to purchase the product relied on [insert 'whatever the agency contended was wrong with the product'] and thus, the defendant misrepresented the product's benefits." Plaintiffs in those cases typically construe the agencies' notice as containing legal conclusions and findings sufficient to state a claim for false advertising or misrepresentation and fail to allege additional facts or have independent verification of their allegations.

Fortunately, federal courts from Florida to California have rejected plaintiffs' counsel's latest attempts to use agency "prior substantiation" enforcement actions (e.g., as the basis to bring a class action under state consumer protection laws. Holding FDA and FTC retain exclusive authority to prosecute claims of "no substantiation," courts have refused to apply the "prior substantiation doctrine" in private class action. The courts reason that false advertising claims cannot be based on a lack of substantiation, because the absence of substantiation in and of itself does not prove that an advertising claim is untrue. See *Franulovic v. Coca Cola Co.* 390

Fed. App'x 125 (3d Cir. 2010); *Fraker v. Bayer Corp*., 2009 WL 5865687 (E.D. Cal. Oct. 6, 2009); *Chavez v Nestle USA*, 2011 WL 2150128 (C.D. Cal. May 19, 2011). The *Fraker* and *Chavez* courts also recognized that the plaintiffs' prior substantiation enforcement actions impermissibly shifted the burden of proof from the plaintiff's requirement to show the claim is false to the defendants to show that their advertising claims, in fact, are substantiated.

Faced with the demise of the prior substantiation claim, plaintiffs are proceeding against defendants using agency warning letters as the sole basis for alleging that advertising or label claims are false and misleading. Although the plaintiff retains the burden of proving that the alleged violative claim is untrue, by using the agency warning letter the plaintiff's attorney improperly side step the requirement to investigate the facts and law. This maneuver may provide the defendant with a significant short-cut, but also provides defendants with some strategy for securing a dismissal.

Where plaintiffs' claims are based entirely on the agency determination (without extensive supporting facts being pled by the plaintiff), the defendant may couple a motion to dismiss with a motion to strike the agency warning letter and all "facts" set forth therein. The court should find that the agency letter is third party hearsay, and without independent supporting facts is insufficient to state a claim, and further, that the hearsay allegations should be stricken. See *Regenerative Sciences, Inc. v. FDA*, 2010 WL 1258010 (D. Colo. Mar. 26, 2010). Plaintiffs' counsel who fail to independently investigate the underlying facts and law and rely solely on agency letters may also violate Federal Rule 11 as well as related state-law statutes. *Garr v. U.S. Healthcare*, 22 F.3d 1274 (3d Cir. 1994).

Although agencies are stepping up enforcement for consumer products through warning letters and consent orders, companies that find themselves in an agency's crosshairs should not feel that they must pay off class-action plaintiffs and their attorneys to buy peace. Defendants in class actions and false advertising litigation can avail themselves of the courts'

refusal to apply the prior substantiation doctrine to claims brought by private plaintiffs and the court's recognition that agency letters are not dispositive of the facts or the law. In the past year, Sedgwick has used appropriate variants of the above strategies to obtain take nothing dismissals in three class action cases that were based on agency enforcement. Until plaintiffs' attorneys begin to research the facts and law – as opposed to crafting copy-cat allegations – defendants have a strong defense to such class actions.

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